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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,019	02/09/2005	Masahiko Tanikawa	TANIKAWA I	7565

1444 7590 12/27/2006
BROWDY AND NEIMARK, P.L.L.C.
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WASHINGTON, DC 20001-5303

EXAMINER

UNDERDAHL, THANE E

ART UNIT	PAPER NUMBER
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1651

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/27/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/524,019

Applicant(s)

TANIKAWA ET AL.

Examiner

Thane Underdahl

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 6,7,9,10 and 13-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8,11,12 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/20/05 and 4/15/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Restriction/Election

Applicant's response to the species election with traverse filed on 11/22/2006 is acknowledged. The applicant elected Group II which includes claims 1-8, 11, 12 and new claim 18. The required species elected is a hematopoietic factor. Claims 6 and 7 are withdrawn as being drawn to non-elected species.

The applicant traverses on the grounds that limitations of Group IV are encompassed in those of Group I. However as the applicant points out group IV includes the phrase "suppressing the formation of associated matter in a protein solution formulation". While the claims of Group I are to "stabilizing a protein-containing solution". The term "associated matter" is far broader than a "protein-containing solution". In cellular functions associated matter could be respiratory gasses or exopolysaccharides if the protein solution formulation are a culture of bacteria.

Also the applicant has requested art showing evidence that no special technical feature exists that unites the claims. Claim 1 is anticipated by U.S. Patent # 6,440,713 who cultures yeast cells under magnetic field lines. Since yeast cells are protein solutions this patent inherently meets the limitations of claim 1.

Therefore, the Restriction/Election requirement is therefore made FINAL and the elected species and the claims they include will now be examined on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 11 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Castle (U.S. Patent # 5,261,874, 1993).

These claims are drawn to a method for stabilizing a protein solution formulation by storing the formulation under magnetic field lines. Claim 3 limits the protein to a physiologically active protein which is further limited in claim 4 to a cytokine which is further limited to a hematopoietic factor.

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Castle teaches the radiation of blood to neutralize foreign organisms or other materials in the blood (col 3, line 55) with electromagnetic fields (col 3, line 37). It is inherent that if foreign organisms and other materials, such as viruses are removed from the blood its longevity will increase and thus its stability. His present invention includes radiating blood that is not to be recirculated to the human or animal. It is inherent that blood not recirculated must somehow be stored.

The blood samples used by Castle will inherently contain physiologically active proteins as well as cytokines and hematopoietic factors.

Therefore the reference anticipates claims 1, 3-5, 11 and 18.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castle et al. as applied to claims 1, 3-5, and 11 above.

Claim 2 is drawn to using a magnetic flux density of 1mT (millitesla) or more in the method of claim 1.

While the art above teaches the use of electromagnetic fields to stabilize a protein solution they do not teach 1mT intensity limited by claim 2. However, M.P.E.P. § 2144.05 II states:

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Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical.

Absent any teaching of criticality by the applicant concerning the amounts listed in claim 2 for the method of claim 1, it would be *prima facie* obvious that one of ordinary skill in the art would recognize that this intensity listed in claim 2 is result effective variable and a matter of routine optimization.

Claim 12 further limits claim 11 by teaching the protein containing solution is a bulk solution for protein production. Castle previously teaches in the rejection above that the blood need not be recirculated to the animal (col 4, lines 40-45). He continues to teach that his method is for treating blood components (col 4, lines 34 and 35) and can be implemented with existing blood processing devices requiring little or no redesign. One such process obvious to one of ordinary skill in the art is blood plasma separation, where having a clean supply is paramount, which is why such thorough patient screening and lab testing is involved after the sample is taken. Since plasma contains proteins and is from the bulk blood solution it would be obvious to one of ordinary skill in the art to use the invention of Castle to stabilize the blood protein containing solution to produce plasma proteins. The motivation and reasonable expectation of success is provided by Castle who teach his invention can be implemented with existing blood processing devices.

Therefore the reference listed above renders obvious claims 2 and 12.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Castle as applied to claims 1-5, 11 and 12 above, and further in view of Cohen (U.S. Patent # 3,308,809, 1967).

The claim is drawn to a protein solution formulation stabilized under the method of claim 1 in a pre-filled syringe.

As mentioned above Castle teach that in their invention blood need not be recirculated back to the animal and must be inherently stored. Castle is silent on how to store the blood. However Cohen et al. teach that blood can be stored and dispensed in a syringe (col 1, lines 8-13). It would be obvious to one of ordinary skill in the art to store the protein solution formulation of blood using the method of Castle in the syringe of Cohen. The motivation and reasonable expectation of success is provided by both Castle who teach that the blood can be removed after being stabilized and by Cohen who teaches that the blood can be stored in his syringe. It would also be obvious to continue to use the method of Castle on the syringe of Cohen to further increase the stability of the blood protein solution formulation.

Therefore the references listed above renders obvious claim 8.

In summary no claims, as written, are allowed for this application.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached during regular business hours, 8:00 to 17:00 EST.

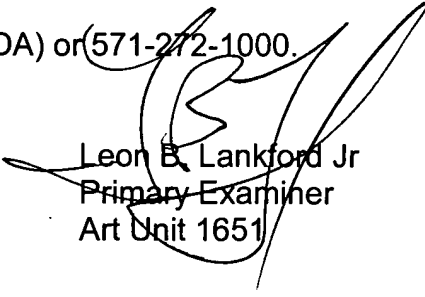
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571-272-1000).

Thane Underdahl
Art Unit 1651



Leon B. Lankford Jr
Primary Examiner
Art Unit 1651